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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,352	09/15/2003	Mingchih M. Tseng	00216-091011 / OB-37H	1599
26161	7590	09/22/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			KRASS, FREDERICK F	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 09/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/663,352	<b>Applicant(s)</b> TSENG ET AL.	
	<b>Examiner</b> Frederick F. Krass	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 45-50 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/15/03</u> . | 6) <input type="checkbox"/> Other: ____  |

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**Specification: Formalities**

Applicant is requested to insert the following heading at an appropriate line on page 8 of the instant specification:

--- Brief Description of the Drawings ---.

**Claims: Informalities**

Claim 47 uses terminology which, while not indefinite *per se*, is in poor form. Specifically, the terms "ethylene vinyl acetate", "styrene/rubber" and "ethylene/propylene" are, strictly speaking, inaccurate, since these are not polymers or resins. The terms should be amended to read "ethylene vinyl acetate polymers", "styrene/rubber polymers" and "ethylene/propylene polymers" in order to place the claims in better form.

**Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-49 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis for the term "resin" at the first line of claim 47 in any of the claims from which it depends. (The term "resin" should be changed to "polymer" in order to obviate this ground of rejection).

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### Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Barclay et al (USP 5,021,053).

The prior art discloses osmotic delivery devices which are matrices comprising an outer layer made from a water-insoluble polymer, e.g. "lightly cross-linked polystyrene derivatives", a.k.a. styrene/rubber polymers (col. 9, lines 27-29, and lines 51 and 52), and inner layers comprising a hydrogel and a drug layer, where the inner layers comprise a water-soluble polymer, e.g. polyethyleneoxide (col. 11, lines 50-54 and 62). The rate of release of the drug is measured by providing a color contrast between the drug and hydrogel layers: see the passage spanning col. 7, line 52 to col. 8, line 24.

Working example 1 (col. 15) discloses as osmotic device containing the drug nyastatin, which is yellow in color (col. 15, line 34) and water-soluble (col. 10, lines 47-49). Working example 2 (col. 16) discloses a similar device containing the antimicrobial agent chlorhexidine diacetate, which is white in color and similarly water-soluble. Since these drugs are colored, water-soluble, and leach from the delivery device upon repeated contact with water as the patient sucks and/or chews on the device (col. 11, lines 51-53), they are "water-leachable colorants that leach from the matrix when the matrix is exposed to water to provide a change in color" as required by the instant claims. When the drug is chlorhexidine, the prior matrix "additionally comprises" an antimicrobial agent and is "adapted to leach colorant corresponding with the depletion of said antimicrobial agent" as required by instant claims 48 and 49. Moreover, in

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monitoring the diminishment in the amount of drug left in the device which occurs as it is released from the device, one is monitoring "wear" of the drug-containing layer as required by instant claim 50.

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tseng (USP 5,349,750) in view of Barclay et al (USP 5,021,053).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

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disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The primary reference discloses shaving systems comprising a blade and a support structure, the support structure including a shaving aid composite. The shaving aid composite comprises a water-soluble polyethyleneoxide shaving aid disposed in a water-insoluble ethylene vinyl acetate matrix, where the shaving aid leaches out from the composite upon exposure to water. See col. 1, lines 39-57. The shaving aid also includes a color dye and antimicrobial agent: see col. 2, lines 27-29. Representative shaving systems are exemplified in the prior art working examples.

The primary reference differs from the instant claims insofar as it does not specifically disclose a shaving system which is sufficiently translucent to permit observation of diminishment in color as the dyed polyethyleneoxide shaving aid, color dye and antimicrobial agent leach out upon exposure to water. (Although the primary reference does not specify what type of "color dye" is used therein, one can reasonably infer that this dye must be water soluble, since it is incorporated into a water soluble component). It is generally known, however, to monitor release

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of an active agent from a matrix by providing a contrast between the fixed and mobile components of a matrix delivery device, selecting materials sufficiently translucent to permit such observation, as taught by the secondary reference. See the passage spanning col. 7, line 52 to col. 8, line 25, and col. 15, lines 59-62. It would have been obvious, therefore, to have manufactured the support structures of the shaving systems of the primary reference from ethylene vinyl acetate polymer materials having sufficient translucence to permit observation of the dyed polyethyleneoxide shaving aid contained therein, motivated by the desire to permit monitoring of shaving aid release in order to permit the user to determine when to dispose of the shaving system due to exhaustion of the shaving aid.

The examiner recognizes that the secondary reference is from the pharmaceutical art, rather than the shaving art. Nevertheless, it is viewed as analogous art because it is "reasonably pertinent to the particular problem with which the inventor was concerned" and because "the matter with which it deals logically would have commended itself to an inventor's attention in considering his problem". See MPEP 2141.01(a), citing In re Oetiker, 777 F.2d 1443, 1446 (Fed. Cir. 1992), and Wang Laboratories Inc. v. Toshiba Corp., 993 F.2d 858 (Fed. Cir. 1993), respectively. Specifically, in this particular fact situation, the "particular problem" with which the inventor was concerned was providing a means for determining when a leachable active agent (shaving aid) present in a delivery matrix (a disposable razor) was exhausted such that the user could know when to discard the used product. The secondary reference is concerned with that same problem, except that it provides the solution within the context of a pharmaceutical application. The solution (providing color contrast) is the same in each instance, so that the matter with which the secondary reference deals (providing color contrast for the delivery of pharmaceutically active agents) "logically would have commended itself to an inventor's attention in considering his problem" (here administering shaving aids from a disposable razor).

2) Claims 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al (USP 5,113,585) in view of Barclay et al (USP 5,021,053).

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The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The primary reference discloses shaving systems comprising a blade and a support structure, the support structure including a shaving aid composite. The shaving aid composite comprises a water-soluble polyethyleneoxide shaving aid disposed in a water-insoluble ethylene vinyl acetate matrix, where the shaving aid leaches out from the composite upon exposure to water. See col. 1, lines 36-39, and col. 2, lines 12-27. The shaving aid also includes a color dye and antimicrobial agent: see for example col. 3, lines 15 and 16. Representative shaving systems are exemplified in the prior art working examples.



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The primary reference differs from the instant claims insofar as it does not specifically disclose a shaving system which is sufficiently translucent to permit observation of diminishment in color as the dyed polyethyleneoxide shaving aid, color dye and antimicrobial agent leach out upon exposure to water. (Although the primary reference does not specify what type of "color dye" is used therein, one can reasonably infer that this dye must be water soluble, since it is incorporated into a water soluble component). It is generally known, however, to monitor release of an active agent from a matrix by providing a contrast between the fixed and mobile components of a matrix delivery device, selecting materials sufficiently translucent to permit such observation, as taught by the secondary reference. See the passage spanning col. 7, line 52 to col. 8, line 25, and col. 15, lines 59-62. It would have been obvious, therefore, to have manufactured the support structures of the shaving systems of the primary reference from ethylene vinyl acetate polymer materials having sufficient translucence to permit observation of the dyed polyethyleneoxide shaving aid contained therein, motivated by the desire to permit monitoring of shaving aid release in order to permit the user to determine when to dispose of the shaving system due to exhaustion of the shaving aid, that method of monitoring being generally known from the secondary reference.

The examiner recognizes that the secondary reference is from the pharmaceutical art, rather than the shaving art. Nevertheless, it is viewed as analogous art because it is "reasonably pertinent to the particular problem with which the inventor was concerned" and because "the matter with which it deals logically would have commended itself to an inventor's attention in considering his problem". See MPEP 2141.01(a), citing In re Oetiker, 777 F.2d 1443, 1446 (Fed. Cir. 1992), and Wang Laboratories Inc. v. Toshiba Corp., 993 F.2d 858 (Fed. Cir. 1993), respectively. Specifically, in this particular fact situation, the "particular problem" with which the inventor was concerned was providing a means for determining when a leachable active agent (shaving aid) present in a delivery matrix (a disposable razor) was exhausted such that the user could know when to discard the used product. The secondary reference is concerned with that same problem, except that it provides the solution within the context of a pharmaceutical application. The solution (providing color contrast) is the same in each instance, so that the

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matter with which the secondary reference deals (providing color contrast for the delivery of pharmaceutically active agents) "logically would have commended itself to an inventor's attention in considering his problem" (here administering shaving aids from a disposable razor).

### Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 45-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-10, 12 and 13 of U.S. Patent No. 5,998,431 in view of Barclay et al (USP 5,021,053).

The conflicting patent claims matrices comprising a water soluble polymer, a water-soluble polymer, and a colorant which leaches upon exposure to water. The claims of the conflicting patent differ from the instant claims insofar as they require a combination of layers having contrasting colors.

It is known to monitor release of an active agent from a matrix by providing a contrast between different layers of a matrix delivery device, selecting materials sufficiently translucent to permit such observation, as taught by the secondary reference. See the passage spanning col. 7, line 52 to col. 8, line 25, and col. 15, lines 59-62. It would have been obvious, therefore, to have used a combination of layers having contrasting colors in manufacturing the matrices recited by the instant claims, in order to aid observation of release of the active agent and water-leachable colorant from the matrices as taught by the secondary reference.

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2) Claims 45-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-22 and 24 of U.S. Patent 5,906,834 in view of Barclay et al (USP 5,021,053).

The conflicting patent claims matrices comprising a water soluble polymer, a water-soluble polymer, and a colorant which leaches upon exposure to water. The claims of the conflicting patent differ from the instant claims insofar as they require a combination of layers having contrasting colors.

It is known to monitor release of an active agent from a matrix by providing a contrast between different layers of a matrix delivery device, selecting materials sufficiently translucent to permit such observation, as taught by the secondary reference. See the passage spanning col. 7, line 52 to col. 8, line 25, and col. 15, lines 59-62. It would have been obvious, therefore, to have used a combination of layers having contrasting colors in manufacturing the matrices recited by the instant claims, in order to aid observation of release of the active agent and water-leachable colorant from the matrices as taught by the secondary reference. Additionally, it would have been obvious to have used polyethyleneoxides of varying molecular weight, including those weights specifically recited by the conflicting patent in various dependent claims, in order to tailor the physical properties and release profiles of the claimed matrices for particular specific applications, motivated by the desire to provide optimal performance.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;  
Tuesday: 10:30AM - 7PM;  
Wednesday: off;  
Thursday: 10:30AM- 7PM; and  
Friday: 10:30AM-7PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

